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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,888	06/29/2001	Tom A. Grigliatti	4810-59380	3346

7590 05/26/2005

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/896,888	<b>Applicant(s)</b> GRIGLIATTI ET AL.	
	<b>Examiner</b> Nancy T. Vogel	<b>Art Unit</b> 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17, 23 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17, 23 and 27-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

**DETAILED ACTION**

Claims 1-17, 23 and 27-33 are pending in the case.

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submissions filed on 2/23/05 and 9/22/04 have been entered.

***Claim Objections***

Claim 12 is objected to because of the following informalities: the claim recites "the selectable marker coding". Presumably, "the selectable marker coding sequence" is intended. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 4-17, 23 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for the reasons made of record in the previous Office action, mailed 4/20/04, and in the Advisory Action, mailed 11/1/04.

Applicants have argued in their arguments submitted 2/23/05, that the specification describes that the shuttle vectors of the present invention can be adapted for use with a variety of antibiotic selection schemes, at page 67, lines 20-21, and therefore the specification "satisfactorily conveys to those skilled in the art that the claimed shuttle vectors are not limited to zeocin, but can be adapted for use with other antibiotic selection schemes" (pages 3-4). While it is agreed that the specification makes this statement, it is maintained that the specification has not described resistance marker genes other than those conferring resistance to a bleomycin/phleomycin-type antibiotic such as Zeocin, which may function in insect and prokaryotic cells. It is noted that the specification contains statements regarding the unpredictability of the use of selection markers, which can include amplification and subsequent instability (pages 25 and 27 of the specification), and discloses that only the disclosed zeomycin marker avoids such undesired properties.

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The Declaration under 37 CFR 1.132 filed 9/22/04, is insufficient to overcome the rejection of claims 1, 4-17, 23, 27-30, based upon 35 USC 112 first paragraph, as set forth in the last Office action because:

The Declaration of Dr. Grigiliatti showing other antibiotic selection schemes, is not found convincing, since the information disclosed therein is not part of the specification and therefore does not remedy the lack of written description, showing that applicant had possession of the invention as claimed, at the time of filing.

For these reasons, the rejection is maintained.

The following is a new rejection necessitated by applicant's amendment:

Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is based on the Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, first paragraph "Written Description published in the Federal Register (Volume 66, Number 4, Pages 1099-1111). Claim 1 is drawn to a shuttle vector in which a prokaryotic promoter sequence is a cryptic promoter with an insect promoter, wherein a selectable marker coding sequence operably linked to said promoter region is capable of expression in both prokaryotic and insect cells to confer a selectable phenotype on cells

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transformed with the shuttle vector. The specification has not defined the term "cryptic promoter", however, it discloses an example wherein the insect Op ie2 promoter is present on a particular vector, expression in an E. coli cell occurs (page 62). (It is noted that it is not clear from the specification whether this Op ie2 promoter acts as a prokaryotic promoter in all vectors, and in all cell types). Claim 30 is a genus claim in terms of a shuttle vector which contains an insect promoter that contains a cryptic prokaryotic promoter sequence. The disclosure is not deemed to be descriptive of the complete structure of a representative number of species encompassed by the claims as one of skill in the art cannot envision all the insect promoters, which contain cryptic prokaryotic promoters, based on the teachings of the specification. While the specification provides an example in which a particular insect promoter, in a particular vector, and in a particular prokaryotic host cell, exhibits promoter activity, there is no disclosure of the precise nucleotides responsible for this activity. Furthermore, there is no structure-function analysis of the disclosed promoter to provide guidance on the essential regions of the promoter for the cryptic prokaryotic promoter activity. Therefore, the specification does not describe the claimed vector comprising a prokaryotic promoter sequence which is a cryptic promoter within an insect promoter in such full, clear, concise and exact terms so as to indicate that Applicant has possession of the product at the time of filing the present application. Thus, the written description requirement has not been satisfied.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 23, and 27-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 2 and by dependence claims 3-17, 23 and 27-30 are vague and indefinite in the recitation of "capable of" because it is unclear what factors are encompassed with the claims to make the gene or promoter capable of or not capable of functioning. The metes and bounds of the claims cannot be determined.

Claim 30 is vague and indefinite in its recitation of "cryptic" because it is unclear what is intended by this term. Therefore, the intended metes and bounds of the claimed subject matter cannot be determined.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Theilmann et al. (Virology 187, 84-96, 1992).

Theilmann et al. disclose a vector for expressing a heterologous protein (chloramphenicol acetyl transferase) comprising an inset promoter which comprises the promoter of the IE1-2 gene of Orgyia pseudotsugata multicapsid nuclear polyhedrosis virus. This promoter contains the IE2B element (page 8 of the specification). Therefore, the reference anticipates the claims.

### ***Conclusion***

No claims are allowed.

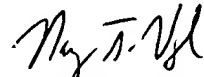
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy T. Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
**NANCY VOGEL, PH.D.**  
**PATENT EXAMINER**